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ORIGINAL SCIENTIFIC REPORT

The Benefits of a Wound Protector in Preventing Incisional Surgical Site Infection in Elective Open Digestive Surgery: A Large-Scale Cohort Study

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Abstract

Background The objective of this study was to evaluate the benefits of wound protectors (WPs) in preventing incisional surgical site infection (I-SSI) in open elective digestive surgery using data from a large-scale, multi-institutional cohort study.

Methods Patients who had elective digestive surgery for malignant neoplasms between November 2009 and February 2011 were included. The protective value of WPs against I-SSI was evaluated.

Results A total of 3201 patients were analyzed. A WP was used in 1022 patients (32%). The incident rate of I-SSI (not including organ/space SSI) was 9%. In the univariate and the multivariate analyses for perioperative risk factors for I-SSI, the use of WP was an independent favorable factor that reduced the incidence of I-SSI (odds ratio 0.73, 95% confidence interval 0.55–0.98. $P = 0.038$). The subgroup forest plot analyses revealed that WP reduced the risk of I-SSI only in patients aged 74 years or younger, males, non-obese patients (body mass index <25 kg/m^2), patients with an American Society of Anesthesiologists score of 1/2, patients with a previous history of laparotomy, non-smokers, and patients who underwent colon and rectum operations. In patients who underwent colorectal surgery, the postoperative hospital stay was significantly shorter in patients with WP than those without WP (median 13 vs. 15 days, $P = 0.040$). In terms of the depth of SSI, WP only prevented superficial I-SSI and did not reduce the incidence of deep I-SSI.

Conclusions WP is a useful device for preventing superficial I-SSI in open elective digestive surgery.

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Abbreviations

ASA	American Society of Anesthesiologists
BMI	Body mass index
CT	Computed tomography
CI	Confidence interval
DI-SSI	Deep incisional surgical site infection
HBP	Hepato-biliary-pancreatic
I-SSI	Incisional surgical site infection
OR	Odds ratio
OS-SSI	Organ/space surgical site infection
SI-SSI	Superficial incisional surgical site infection
WP	Wound protector

Introduction

An incisional surgical site infection (I-SSI) is one of the common postoperative morbidities after digestive surgery [1–3]. The incidence of I-SSI increases not only the cost of treatment but also the risk of incisional hernia as a long-term complication [4]. Previous studies have reported numerous independent risk factors for I-SSI. The improvement in intraoperative wound management is one of the most important methods for reducing I-SSI [1–3, 5–7]. Intraoperative wound management has been reported to have an impact on the incidence of I-SSI and includes the use of antibiotic prophylaxis [1, 2, 5], skin preparation [1, 2, 5, 8], skin drape [9], operative double gloving [2, 10–12], body temperature [2, 13], wound length [7], subcutaneous lavage before closure [14–16], subcutaneous drainage [17–19], methods of skin suture (subcuticular absorbable suture) [5, 17, 20, 21], and skin wound dressing [22].

Generally, I-SSI is associated with a number of local bacteria [23, 24]. In an experimental mouse model, 10^5 bacteria in 1 g of tissue is sufficient to induce I-SSI [23]. To reduce the incidence of I-SSI, it is necessary to prevent surgical wound exposure to bacteria. In this regard, the use of a wound protector (WP) during the operation is thought to protect against exposure to bacteria, especially enteric bacteria, on the wound edge while performing gastrointestinal surgery [24, 25]. In fact, the latest guidelines recommend the use of a WP as for the prevention of I-SSI (evidence level I) [2].

Although several randomized control trials [26–31] and meta-analyses [32–36] have reported that WP reduced the incidence of I-SSI, these trials had a small number of patients ($n = 64$–729), and there is no prospective, large-scale (more than 1000 patients) study of the clinical value of WPs. In this study, the data from a prospective and large-scale multi-institutional cohort study (including more than 3000 patients) were used to evaluate the clinical value of WPs for I-SSI in open elective digestive surgeries for malignant neoplasms.

Methods

Patients

This study analyzed the data from a subset of patients enrolled in a prospective observational study for incisional hernia and incisional surgical site infections [4, 7]. The main protocol was approved by the institutional review boards of Nagoya University Graduate School of Medicine and the participating hospitals, and the study design was registered with the Infrastructure for Academic Activities with the University Hospital Medical Information Network Identifier (UMIN000004723, http://www.umin.ac.jp/ctr/index/htm). Informed consent was obtained from each patient before enrollment in the study.

In this cohort, patients who underwent open abdominal surgery between November 2009 and February 2011 at Nagoya University Hospital and the 19 affiliated hospitals were enrolled. The eligibility criteria for this study were as follows: (1) 20 years or older; (2) open (not laparoscopic) intraabdominal digestive organ (the stomach, colorectal, liver, gallbladder, bile duct, and pancreas) resections for malignant tumors; (3) no incision other than in the abdomen or perineum; and (4) no artificial implantation. Patients who underwent laparoscopic or laparoscopy-assisted surgeries were excluded. Patients without tumor resection (e.g., bypasses of the digestive tract and exploratory laparotomies) were also excluded.

Monitored perioperative factors

Clinical data, including preoperative, intraoperative, and postoperative factors, were prospectively recorded by the surgeons who were in charge of data collection at each hospital. Prospectively monitored preoperative clinical data included age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score, previous medical history (laparotomy and chemotherapy), smoking status, and subcutaneous fat thickness. Subcutaneous fat thickness was preoperatively measured with computed tomography (CT) at the thickest incisional location.

Prospectively monitored intraoperative factors included operative procedure (stomach, colon and rectum, or hepato-biliary-pancreatic surgeries), operative time, blood loss, wound length, intraoperative allogeneic blood transfusion, type of incision (midline/pararectal/transverse/inverted L/Mercedes), the use of a WP, subcutaneous lavage, the type of skin closure, and skin wound dressing.

The protection method of the wound edge was freely chosen according to the policy of each institution or surgeon. In this study, only patients with plastic WPs were included in the WP group. Other patients who were operated on with cloth towel wound coverage or no coverage were included in the no-

WP group. The plastic WP was either the dual ring WP (Alexis™ wound, Applied Medical Resources Corporation) or the single ring WP (Steri-Drape™ Wound Edge Protector, 3 M Health Care).

The endpoint of this study was to evaluate the clinical value of WPs in preventing the incidence of I-SSI (not including organ/space SSI, OS-SSI). Only the condition of the abdominal wound was used for the data analysis. The Centers for Disease Control and Prevention definitions of SSI were employed when monitoring the incidence of I-SSI [1]. I-SSI included both superficial incisional surgical site infection (SI-SSI) and deep incisional surgical site infection (DI-SSI). SI-SSI was diagnosed when the incidence occurred within 30 days after the operation and involved the skin and subcutaneous tissue with one of the following conditions: (1) purulent discharge; (2) organisms isolated from an aseptically obtained culture of fluid or tissue; (3) signs or symptoms of infection, including pain/tenderness, localized swelling, redness/heat, and an open wound; or (4) diagnosis of SI-DDI by a surgeon or attending physician [1]. DI-SSI was diagnosed when the infected wound involved fascial and muscle layers but not the organ space [1].

Data collection and follow-up

After surgery, patients were monitored daily during their hospital stay, and all perioperative data were prospectively recorded in a database. After discharge, patients were followed up for at least 30 days in an outpatient clinic.

Statistical analysis

In the univariate analysis, differences among categorical variables were analyzed using the Chi-square test. The logistic regression model (stepwise forward) was used to calculate the odds ratio (OR) with 95% confidence intervals (CIs). In the multivariate analysis, all possible risk factors were evaluated for the analysis. A subgroup analysis for the incidence of I-SSI was calculated with Fisher's exact test. *P* values of less than 0.050 were considered statically significant. The data analysis was performed using IBM SPSS statistical software (version 21; SPSS Japan Inc.).

Results

Clinical characteristics of the study patients

Between November 2009 and February 2011, a total of 4305 consecutive patients were enrolled in the main study: a prospective monitoring program for the incidence of incisional hernia in abdominal surgery [4]. Among them, 3201 patients fulfilled the eligibility criteria of this study (Table 1). The median follow-up period was 461 days

Table 1 Clinical characteristics of the patients ($n = 3201$)

Factors	*N* (%) or median [interquartile range]
Preoperative factors	
Age (years old)	69 [62–76]
Gender	
Male	2101 (66%)
Female	1100 (34%)
Body mass index (kg/m^2)	21.9 [19.7–24.2]
American Society of Anesthesiologists score	
1	1319 (41%)
2	1742 (54%)
3	137 (4%)
4	13 (1%)
Previous history of laparotomy	753 (24%)
Preoperative chemotherapy	208 (6%)
Smoking within 1 month	753 (24%)
Subcutaneous fat thickness by CT (cm)	1.7 [1.2–2.3]
Operative factors	
Operative procedure	
Stomach	993 (31%)
Colon and rectum	1439 (45%)
Hepato-biliary-pancreatic	769 (24%)
Operative time (min)	199 [145–281]
Blood loss (ml)	290 [120–663]
Wound length (cm)	19 [15–23]
Intraoperative allogeneic blood transfusion	367 (9%)
Type of incision	
Midline	2605 (81%)
Pararectal	144 (5%)
Transverse	48 (1%)
Inverted L	330 (11%)
Mercedes	74 (2%)
Wound protector	1022 (32%)
Subcutaneous lavage	2331 (73%)
Type of skin closure	
Interrupted transdermal suture	1346 (42%)
Subcuticular suture	1855 (58%)
Skin wound dressing	1447 (45%)
Postoperative complications	
All complications	977 (31%)
Surgical site infections	644 (21%)
Incisional surgical site infection	280 (9%)
Superficial incisional surgical site infection	229 (7%)
Deep incisional surgical site infection	51 (1%)
Organ/space surgical site infection	410 (13%)
Remote infection	202 (6%)
In-hospital death	21 (1%)
Postoperative hospital stay (day)	14 [2–255]

Table 2 Univariate analyses of perioperative risk factors for I-SSI ($n = 3201$)

Factors	*N*	No. of I-SSI (%)	*P* value
Preoperative factors			
Age (years old)			0.312
≤74	2223	187 (8)	
≥75	978	93 (9)	
Gender			0.870
Male	2101	185 (8)	
Female	1100	95 (8)	
Body mass index (kg/m^2)			0.040
<25.0	2594	218 (8)	
≥25.0	607	62 (10)	
ASA score			0.018
1/2	3061	260 (9)	
3/4	140	20 (14)	
Previous history of laparotomy			0.002
Absent	2448	193 (8)	
Present	753	87 (12)	
Preoperative chemotherapy			0.578
Absent	2993	264 (9)	
Present	208	16 (8)	
Smoking (within 1 month)			0.502
Absent	2963	262 (9)	
Present	238	18 (8)	
Subcutaneous fat thickness by CT (cm)			0.034
<3.0	2998	254 (9)	
≥3.0	203	26 (13)	
Operative factors			
Operative procedure			<0.001
Stomach	993	28 (3)	
Colon and rectum	1439	174 (12)	
Hepato-biliary-pancreatic;	769	78 (10)	
Operative time (h)			0.002
<4.0	2089	160 (8)	
≥4.0	1112	120 (11)	
Blood loss (ml)			0.005
<500	2136	166 (8)	
≥500	1065	114 (11)	
Wound length (cm)			<0.001
<20.0	2099	142 (7)	
≥20.0	1102	138 (13)	
Intraoperative allogeneic blood transfusion			0.160
Absent	2834	241 (9)	
Present	367	39 (11)	
Type of incision			0.200
Midline	2605	220 (8)	
Non-midline	596	60 (10)	
Wound protector			0.028
No use	2179	207 (10)	
Use	1022	73 (7)	
Subcutaneous lavage			0.311
Absent	870	69 (8)	
Present	2331	211 (9)	
Type of skin closure			0.381
Interrupted transdermal sutures	1346	128 (10)	
Subcuticular sutures	1855	152 (8)	
Skin wound dressing			0.562
Absent	1754	158 (9)	
Present	1447	122 (8)	
Hospital size			0.004
High-volume center	1563	114 (7)	
Non-high-volume center	1638	166(10)	

ASA score American Society of Anesthesiologists score, *CI* confidence interval, *I-SSI* incisional surgical site infection, *OR* odds ratio

(range 2–1105), and a total of 3113 patients (97%) were followed up for 30 or more days. The follow-up period was less than 30 days in 88 patients (3%) because of the loss of revisits in the outpatient department ($n = 42$), reoperation ($n = 38$), and postoperative death ($n = 8$).

A WP was used in 1022 patients (32%). For the remaining 2179 patients, a cloth towel was used ($n = 1868$) or the wound was exposed to the air without the use of any wound coverage ($n = 311$). I-SSI occurred in 280 patients (9%), including 229 patients (8%) with SI-SSI and 51 patients (1%) with DI-SSI.

Among 280 patients with I-SSI, the microbiological culture from infectious site was performed in 131 patients (47%) including 43 with WP and 88 without WP. The skin-derived bacteria were detected in 44 patients (13 with WP and 31 without WP). The gut-derived bacteria were detected in 85 patients (34 with WP and 51 without WP).

Univariate and multivariate analyses for perioperative risk factors for I-SSI

Among the possible risk factors (including 8 preoperative, 10 operative factors, and 1 hospital size), a total of 10 factors were significantly associated with I-SSI in the univariate analysis (Table 2). Those factors included 4 preoperative factors (high BMI, high ASA, a previous history of laparotomy, and thick subcutaneous fat by CT), 5 operative factors (colon and rectum or hepato-biliary-pancreatic surgery, a long operative time, great blood loss, a long wound length, and no use of WP), and hospital

Table 3 Multivariate analyses of perioperative risk factors for I-SSI ($n = 3201$)

Factors	OR (95% CI)	*P* value
Operative procedure		<0.001
Colon and rectum	4.72 (3.13–7.13)	<0.001
Hepato-biliary-pancreatic	2.41 (1.49–3.90)	<0.001
Wound length (cm) ≥ 20.0 cm	1.86 (1.39–2.47)	<0.001
ASA score 3 + 4	1.68 (1.01–2.80)	0.045
Operative time ≥ 4.0 h	1.54 (1.15–2.05)	0.003
Previous history of laparotomy	1.46 (1.10–1.95)	0.009
Wound protector use	0.73 (0.55–0.98)	0.038
High-volume center	0.67 (0.52–0.87)	0.003

ASA score American Society of Anesthesiologists score, *CI* confidence interval, *I-SSI* incisional surgical site infection, *OR* odds ratio

volume. All possible risk factors were included in the multivariate analysis using the logistic regression model (stepwise forward). Consequently, 7 factors were identified as being independent risk factors for I-SSI (Table 3). These factors included the operative procedure (colon and rectum, OR 4.72 and hepato-biliary-pancreatic, OR 2.41), a wound length 20 cm or longer (OR 1.86), an ASA 3/4 (OR 1.68), an operative time of 4.0 h or longer (OR 1.54), a previous history of laparotomy (OR 1.46), WP use (OR 0.73), and high-volume center (OR 0.67).

Subgroup analysis for the use of WP

The subgroup forest plot analyses revealed a significant risk reduction in I-SSI when using WP in patients 74 years or younger, males, non-obese patients (BMI less than 25 kg/m^2), patients with an ASA of 1/2, patients with a previous history of laparotomy, non-smokers (within 1 month), patients who underwent an operation of the colon and rectum, and patients without OS-SSI (Fig. 1).

The impact of WP use on the incidence of I-SSI

Although the use of a WP did not have an impact on the incidence of DI-SSI, it tended to reduce the incidence of SI-SSI (Table 4). In particular, the incidence of SI-SSI was significantly lower when WP was used in colon and rectum surgeries. The postoperative hospital stay was also significantly shorter when WP was used in colon and rectum surgeries.

Discussion

This study focused on the clinical value of WP use in preventing the incidence of I-SSI in open digestive surgery, including gastric, colorectal, and hepato-biliary-pancreatic surgeries. The incidence of I-SSI was 9% in all patients (8% for SI-SSI and 1% for DI-SSI). The use of a WP independently decreased the incidence of I-SSI in all digestive surgery. Subgroup analyses indicated that the use of a WP significantly reduced the incidence of SI-SSI in colorectal surgery.

Although the latest meta-analysis [32–36] reported that WP was useful in preventing I-SSI events, no prospective large-scale (more than 1000 patients) study had investigated the clinical value of WPs. The number of patients included in this study was equal to or more than the sample size of recently published meta-analyses ($n = 939$–3695) [32–36]. Moreover, in this cohort, almost all patients (97%) were followed up for more than 30 days, and I-SSI after discharge was also evaluated at the outpatient clinic. This cohort was useful in evaluating the clinical impact of WP use in abdominal surgery.

The use of a WP protects the incisional site from bacteria [24, 25]. The bacteria that may contaminate the surgical wound are classified into two categories: skin bacteria (e.g., Staphylococcus aureus) and enteric bacteria (e.g., Escherichia coli). A previous study (about bacterial colonization on the surface of WP in open gastrointestinal surgery) reported that the frequency of positive bacterial cultures was significantly lower on the outside surface of the WP (incisional skin site) than that on the inside surface of the WP (abdominal cavity) [25]. The same study also demonstrated that the use of a WP significantly reduced wound exposure to enteric bacteria (not skin-derived bacteria), especially in colorectal surgery [25]. The subgroup analyses of this study and other studies [29–31] also demonstrated that the use of a WP decreased I-SSI, especially SI-SSI, in open colorectal surgery. The microbiological culture of this study detected the bacteria derived from both skin and gut. The gut-derived bacteria were detected approximately 80% (24 out of 43) in the patients who developed I-SSI in the WP group. These results indicated that the WP usage was not adequate to avoid the bacterial contamination from the gut and that the other intraoperative procedures and techniques are necessary to further prevent I-SSI.

In this study, only patients for whom plastic WP was used during the operation were included in the WP group. Patients who had a cloth towel used for wound coverage were included in the no-WP group. Although there was no significant difference in the incidence of I-SSI between the patients with no wound coverage (10%) and those with cloth towel coverage (9%), the patients with plastic WP had a significantly lower incident rate of I-SSI (7%) than the other two groups. These results correspond with the observation in a previous randomized controlled study comparing the group with intraoperative wound coverage with WP and that with a surgical towel [31]. It is

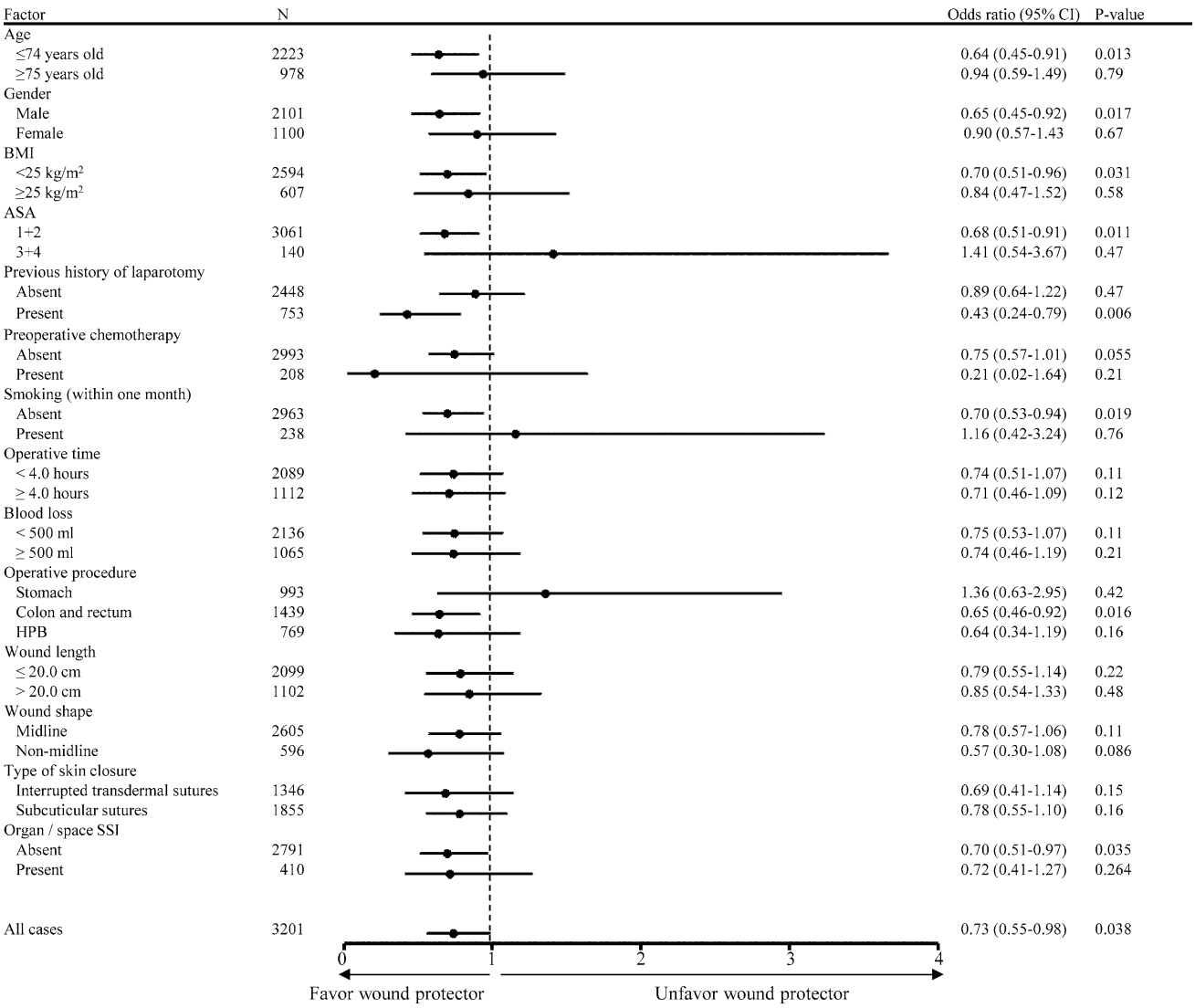

Fig. 1 A forest plot of the subgroup analyses for the use of a wound protector in preventing incisional surgical site infection (I-SSI). *ASA* American Society of Anesthesiologists, *BMI* body mass index, *CI* confidence interval, *HBP* hepato-biliary-pancreatic

Table 4 Relationship between the use of a wound protector and the depth of incisional surgical site infection/length of postoperative hospital stay

	All patients			Colon and rectum		
	Wound protector, *n*		*P* value	Wound protector, *n*		*P* value
	No use, 2179	Use, 1022		No use, 915	Use, 524	
I-SSI						
Absent	1972 (91%)	949 (93%)	0.059	800 (86%)	475 (91%)	0.040
SI-SSI	172 (8%)	57 (6%)		106 (12%)	39 (7%)	
DI-SSI	35 (1%)	16 (1%)		19 (2%)	10 (2%)	
Postoperative hospital stay (days)	15 (2–255)	15 (6–182)	0.23	15 (2–255)	13 (6–135)	<0.001

DI-SSI deep incisional surgical site infection, *SI-SSI* superficial incisional surgical site infection

speculated that the contaminated exudates during surgery may infiltrate the cloth towel and reach the wound edge, thus leading to the higher incidence of I-SSI. Therefore, the use of a cloth towel is not recommended for covering the wound edge [31].

Almost all previous studies on the incidence of SSI did not differentiate the depth of the SSI (i.e., SI-SSI and DI-SSI). Only this study and the latest meta-analysis demonstrated that the use of WP reduced the incidence of SI-SSI rather than that of DI-SSI [36]. The results in this study imply that the use of WP is not effective in preventing the incidence of deep layer wound infection. Further investigations are necessary to identify wound management methods to prevent the incidence of DI-SSI.

The use of a WP reduced not only the incidence of I-SSI but also the length of the postoperative hospital stay in colorectal surgery patients. The prevention of the incidence of I-SSI may also reduce the cost for wound management such as drainage, bacterial culture, antibiotics use, and others. In our institution, the average length of hospital stay after colorectal surgery is approximately 15 days, and the average daily cost for a hospital stay, excluding the surgery-related costs, is approximately $360. The average hospital stay was 2 days shorter in patients with WP use compared to those without WP use. The cost of a WP is approximately $80. Therefore, the use of WP may have the potential to save approximately $640 ($=360 \times 2 - 80$) of medical costs per patient.

The subgroup analyses demonstrated that WP had a favorable effect in preventing I-SSI in the groups of younger age 74 years or less, no obesity (BMI less than 25 kg/m^2), with an ASA 1/2, absent of previous history of laparotomy, and who were non-smokers (within 1 month). Those groups were thought to be of low risk of I-SSI. In high risk groups for I-SSI (e.g., older age, obesity, and an ASA of 3/4), the use of a WP may not be sufficient for preventing the incidence of I-SSI. In terms of type of SSI, although the WP usage reduced the incidence rate of I-SSI among the patients without concomitant OS-SSI, it did not reduce the incidence of I-SSI in patients with OS-SSI. It is speculated that the effect of WP is modest, and an additional preventive treatment is required to reduce the incidence of I-SSI in patients with concomitant OS-SSI.

Other independent risk factors for I-SSI identified by the multivariate analysis included a high ASA score, a previous history of laparotomy, operative procedures (colorectal and hepato-biliary-pancreatic surgery), operative time, and the wound length. However, these factors are generally unchangeable because they are determined by the patients' condition, including their disease status. The use of WP is the only factor that can be managed by the surgeon's ingenuity.

There are several limitations in this study. The primary endpoint of the original study was the rate of incisional hernia after abdominal surgery [4], and this study was thought to be a secondary post hoc analysis. Nevertheless, the number of registered patients in this study is equal to the number in the latest meta-analyses [33, 34, 36]; thus, the results are meaningful. Another limitation is that this study was not a randomized controlled trial and that the use of WP was depending on institutional policy or surgeon's preference. Therefore, we performed a sensitivity analysis in addition to the main analysis to offset the limitation of variable WP usage rate among institutions. Consequently, it was evident that the use of WP was valuable in reducing the incidence of I-SSI.

Conclusion

The WP is a useful device for preventing I-SSI in open elective digestive surgery.

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Compliance with ethical standards

Conflicts of interest From October 2009 to September 2013, Ethicon Japan KK paid Nagoya University Graduate School of Medicine through the endowed chair's (The Division of Surgical Infection) employment of Keita Itatsu, Yukihiro Yokoyama, and Gen Sugawara. The other authors had no conflicts of interest.

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